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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,989

05/25/2005

Jenny P Y Ting

5470-368

4540

20792 7590 09/30/2008  
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EXAMINER

BURKHART, MICHAEL D

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

09/30/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/511,989	<b>Applicant(s)</b> TING ET AL.	
	<b>Examiner</b> MICHAEL BURKHART	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 4, 16, 20, 27-54 and 57-60 is/are pending in the application.
- 4a) Of the above claim(s) 27-54 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 57 and 58 is/are allowed.
- 6) ☒ Claim(s) 4, 16, 20, 59 and 60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/28/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/28/2008 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 16, 20, 59 and 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 4, 16, 20, 59 and 60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding the polypeptide of SEQ ID NO: 18 or amino acids 1-921 of SEQ ID NO: 20, does not reasonably provide enablement for any other CATERPILLER 11.3 polypeptide or any functional fragment of a CATERPILLER 11.3 polypeptide. Furthermore, the specification does not enable the detection of the modulation

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of an activity of the CATERPILLER 11.3 polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. **This rejection is maintained for reasons set forth in the Office Actions dated 4/23/2007, 12/31/2007, and for reasons set forth below.**

Regarding new claims 59 and 60, the specification does not describe any “function” of CLR11.3 at the molecular level. The only functional information for CLR11.3 provided in the specification (page 114, lines 1-13) is that overexpression of CLR11.3 in a cell carrying an NF- $\kappa$ B-dependent reporter gene reduces induction of the reporter gene in response to overexpression of MyD88 or NIK, i.e. it appears to have a negative regulatory activity in certain inflammatory signaling pathways. However, the specification does not disclose where specifically in the pathway CLR11.3 acts, or what it does or interacts with at the molecular level to reduce induction of expression from an NF- $\kappa$ B-dependent promoter. It is not clear whether inhibition of MyD88- or NIK-mediated induction of an NF- $\kappa$ B-dependent promoter are the only biological activities of CLR11.3. The specification does not describe a “function” known to be associated with the leucine -rich repeats of CLR11.3. Also, the specification does not disclose what part or parts of CLR11.3 are required for the disclosed activities. With respect to new claim 60, the specification does not teach that CLR11.3 has the function of modulating a TOLL-like receptor pathway itself, nor does the specification teach any changes in sequence of CLR11.3 that would confer such an activity.

Except for the general effects on induction of NF- $\kappa$ B-mediated expression possessed by the entire human CLR11.3, the specification does not describe the other presumed biological

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activities or assays to detect the activities, much less “functional fragments” that possess at least one of these unknown activities. Consequently, there is no evidence that Applicant was in possession of any functional fragments of the disclosed human CLR11.3 polypeptide, and identifying such fragments would require undue experimentation to first identify just what those activities are and then determine what fragments possessed the activities. Indeed, such knowledge was not available until 2008 (see Moore et al, 2008, cited by applicants), underlining that the invention was not enabled or described commensurate in scope with the claims until after the desired filing date (4/30/2002).

***Response to Arguments***

Applicant's arguments filed 4/28/2008 have been fully considered but they are not persuasive. Applicants essentially assert that: 1) Moore et al (2008) teaches that certain domains of the CATERPILLAR 11.3 are involved in the interaction with MAVS; 2) the claims have been amended to remove the "functional" language.

Regarding 1), a reference published in 2008 cannot serve to enable an application with a filing date of 4/30/2002.

Regarding 2), it is noted that applicants correctly assert that the amendments do not have a narrowing effect (page 10 of the remarks, second full ¶). Thus, it unclear how, if the scope of the claims remains unchanged or is broader, these amendments can somehow overcome this rejection. The scope of the claims, read in light of the specification and relevant art, clearly encompasses functional proteins and fragments of such proteins. For example, the method claims 59 and 60 clearly require them. Furthermore, if applicants intend to assert that the claims

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do not encompass functional polypeptides, then the issue of utility under 35 USC 101 arises.

What specific and substantial use do non-functional proteins have?

### ***Conclusion***

Claims 57 and 58 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL BURKHART whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Burkhardt/

Primary Examiner, Art Unit 1633